

State of Connecticut 4 '99 APR 22 AM 16  
**HOUSE OF REPRESENTATIVES**  
STATE CAPITOL  
HARTFORD, CONN. 06106-1591

**REPRESENTATIVE TERRY BACKER**  
ONE HUNDRED TWENTY-FIRST DISTRICT

125 JEFFERSON STREET  
STRATFORD, CONNECTICUT 06497  
TELEPHONES  
HOME: (203) 378-8399  
CAPITOL: (860) 240-8585  
1-800-842-8267

VICE-CHAIR, APPROPRIATIONS COMMITTEE  
MEMBER, ENVIRONMENT COMMITTEE  
MEMBER, LABOR COMMITTEE

April, 16 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane , Room 1061  
Rockville, MD 20852

Re: Federal Register Notice  
Performance Standards for Vibrio vulnificus, Request for comments  
Docket No. 98P-0504

Dear Sir/Madam:

I am opposed to the petition of Center for Science in the Public Interest (CSPI) to require post harvest treatment of shellfish and to set a limit of undetectable for the presence of *Vibrio vulnificus* (V.v.). The petitioner's goal of post harvest treatment of oysters and clams to prevent the extremely rare cases of infection caused by V.v. over reaches the any sensible interpretation of public health protection. Particularly, when considering the historic and established guidelines in regulating normally injurious substances, which V.v. is not.

The naturally occurring organism V.v. is virtually ubiquitous and of no danger to healthy people. Claims have been made that upwards to 30 million people may be in the at risk group for infection from V.v. (included in the alleged at risk population is any person who consumes 2 or more alcoholic beverages per day). Despite this claim, and the extrapolations made, it is clear from our experience with the illness that most people who have become ill, or have succumbed, have had advanced liver disease. The infectious dose for V.v. is unknown. We do know however, that normally healthy people can consume shellfish that host very high population levels of V.v. without any ill effect. Every year hundreds millions of oysters and clams are sold for raw consumption, yet the number of illnesses consistently numbers between zero and twenty. Just this fact alone demonstrates that the general public is not at risk of infection from V.v. by consuming raw shellfish (V.v. infections contracted from beach bathing puncture wounds significantly exceed the number from consumption).

V.v. as an adulteration or an additive from alleged mishandling is misguided and wrong. Since no infectious dose is known for the organism the assertion that levels increased above natural harvest levels as a causative factor in illnesses of the at risk group is solely a leap of faith. It is thought, however, that an infectious dose for the at-risk group is probably very high.

98P-0504

C184

The market for raw shellfish is the economic backbone of the shellfish producing community. Since V. v. is not normally injurious to the general population, there is no justification to set any level, undetectable or otherwise. A common policy used in public health and safety is to allow the use of products that may result in one in one million deaths per year (such as gasoline). If this were not the case the United State's economy would grind to a halt. Infection from V. v. is many magnitudes lower than that standard which is broadly used in our country.

To set any limits on V.v., an organism that offers no risk to the greatest percentage of consumers, would change the standards on which our public health policies have been founded. In turn, that would place FDA in a role as everyone's personal physician. A role it can not perform.


It would be wrong for FDA to deny the shellfish consuming public who are not at risk from V.v. the right to eat shellfish raw. All things, are simply not, for all people. Currently available post harvest treatments, that are unnecessary for the vast majority of people, have produced a product the oyster-consuming public has not embraced. Consumers who may have underlying conditions should not eat raw shellfish. However, the fact that some people should not eat raw shellfish should in no way dictate how normally healthy people should enjoy their food.

The concern of CSPI to reduce the illnesses from V. v. has also been a focus of the shellfish producing community for a number of years. Shellfish producers have responded to the concerns of V. v. in an assertive and directed manner. The shellfish producing community clearly wants to produce a safe product for the general population (it is in their own moral and economic interest to do so). They have manifested this desire by showing a willingness to educate the at risk community and have helped obtain money for the Interstate Shellfish Sanitation Conference (ISSC) to educated the at risk public not to eat raw shellfish. The shellfish community has attempted to target and reach the groups most at risk.

In summation, V.v. is by no means normally injurious to the general population. Any level of increased presence of V.v. above natural harvest levels can not be considered an adulteration or additive since no infectious dose is known. In any event, increased V.v. levels beyond the widely varying natural levels are still not a threat to the general population. Therefore, FDA should not set any limits on the presence of V.v. in shellfish. The effect of setting any limits would be to eliminate the shellfish producing community and with it the; cultural, economic and food values this hard working community provides for our society.

In the interest of disclosure I am a small-scale shellfish producer and an executive board member of the Interstate Shellfish Sanitation Conference. I write this letter on behalf of several hundred shellfishers who are my constituents and that of myself.

Sincerely,

  
Terry Backer  
State Representative

Cc: Congresswoman Rosa DeLauro  
Senator Joseph Lieberman  
Congressman Sam Giedjensen

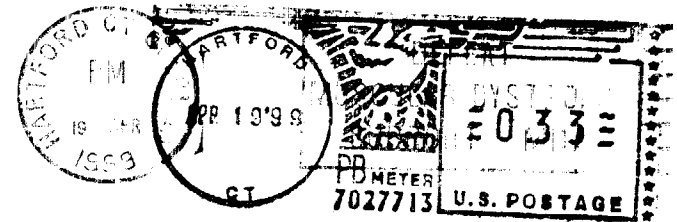
Congressman Christopher Shays  
Senator Chris Dodd  
Honorable John G Rowland, Governor



**State of Connecticut**  
**HOUSE OF REPRESENTATIVES**

STATE CAPITOL  
HARTFORD, CONNECTICUT 06106-1591

REPRESENTATIVE TERRY BACKER  
ONE HUNDRED TWENTY-FIRST DISTRICT



Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane , Room 1061  
Rockville, MD 20852

20857-0001

